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Rene De Clerk

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EXAMINER

EIDE, HEIDI MARIE

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3732

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,824	Applicant(s) DE CLERK, RENE	
	Examiner HEIDI M. EIDE	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-6, 8-10 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (4,349,498) in view of McCrory et al. (6,333,971).
2. Ellis teaches a method to determine the position of a dental implant which is fixed in the bone of the jaw of a person composing the steps of fixing at least one marker element which produces a strong contrast in imaging techniques to an end of the implant, whereby the marker element is situated at a distance from the end, generating an image of the jaw by means of x-rays wherein the jaw contains the implant with the marker element, determining the position of the marker element in relation to the jaw on the basis of the image which is formed by the x-ray and identifying the position of the implant from the observed position of the marker element (col. 7, ll. 44-51). Ellis teaches the invention as substantially claimed and discussed above, however, does not specifically teach attaching the marker element to the implant in a detachable manner.
3. McCrory teaches attaching the marker element to a free end of the implant in a detachable manner (fig. 1A, see abstract). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify means of attachment taught by Ellis with the detachable means taught by McCrory as a matter of obvious design

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choice since McCrory teaches a permanent attachment and detachable attachment of the marker element (see abstract).

4. Ellis further teaches the marker element contains tantalum (col. 3, ll. 40-41).

With respect to claim 22, Ellis does not specifically teach the method for determining the position of the implant in relation to the jaw comprises calculating an exact position of the implant on a longitudinal axis of the implant on the basis of a previously determined distance between the marker element and the free end of the implant, however, it would have been obvious to one having ordinary skill in the art to use any known method of calculating a position in relation to a marker element in the art to determine the position of the implant. Ellis teaches the invention as substantially claimed and discussed above, however, does not specifically teach the marker is a spherical marker, fixing a support with the marker element to the implant in a detachable manner and fixing the support with the marker element to the free end of the implant such that this support extend in the prolongation of the implant and the marker element is situated at a distance for the free end, wherein the implant has a central axis defined by a line through the center of the marker and the method of determining the orientation and position of the central axis as claimed in claim 5 and wherein the imaging means is computer tomography and wherein the support is made of a material which is transparent to x-rays.

5. McCrory teaches the marker element is a spherical marker (col. 5, ll. 39-43). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify shape of the marker element taught by Ellis with the spherical shape

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taught by McCrory in order to find easily find the centroid. McCrory further teaches the imaging means is computer tomography (see abstract), the support is made of a material which is transparent to x-rays, fixing a support with the marker element to the implant in a detachable manner and fixing the support with the marker element to the free end of the implant such that this support extend in the prolongation of the implant and the marker element is situated at a distance for the free end (fig. 1A). McCrory further teaches the implant has a central axis, the orientation and position of the central axis being determined by defining a straight line through a center point of the marker element which is parallel to a longitudinal side of the formed image of the support (fig. 1A). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify means of attachment means of the marker taught by Ellis with the detachable attachment means taught by McCrory as a matter of obvious design choice since McCrory teaches a permanent attachment and a detachable attachment including a support of the marker element (see abstract). As to claims 5-6, Ellis/McCrory does not specifically teach the method comprising the step of determining the orientation and position of the central axis of the implant by defining the center of gravity of pixels representing the implant or the support in the image as well as the center of gravity of the image of the marker element and determining the position of the implant in relation to the jaw on the basis of the orientation and the position of the axis of the implant and the distance between the marker element and the free end of the implant, however, it would have been obvious to one having ordinary skill in the art at the time of the invention to use any known mathematical method in determining the orientation and

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position the central axis of the implant and the position of the implant in relation to the jaw.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (4,349,498) in view of McCrory et al. (6,333,971) as applied to claim 1 above, and further in view of Hattori (5,989,258).

7. Ellis/McCrory teaches the invention as substantially claimed and discussed above, however, does not specifically teach a second marker element is fixed in relation to the implant with a center portion which is not situated on the central axis of the implant wherein the basis of the observed position of the second marker elements, the angular position of the implant in relation to the central axis is determined.

8. Hattori teaches multiple markers 57 fixed in relation to a proposed implant 5 with a center point in which is not situated on the central axis of the implant 5 wherein on the basis of the observed position of the second marker element, the angular position of the implant in relation to the central axis is determined and the support is made of a material which is transparent to x-rays as illustrated in fig. 8 (col. 5, ll. 21-27, col. 7, ll. 5-13). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the marker of Ellis/McCrory with the multiple markers of Hattori in order to provide more references for determining positions and directions of the implant.

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9. Claims 15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sala Meseguer (6,093,023).

10. Sala teaches a support (35/38) with a marker element (36) capable of determining a position of a dental implant which is fixed to the jaw of a person, in relation to the jaw, wherein the marker elements is capable of producing a strong contrast in an image generated by x-rays or magnetic resonance, wherein the support has means at one far end to be fixed to the implant (fig. 17) in a detachable manner, whereas the other far end of the support comprises the marker element (fig. 17), wherein the means for fixing the support to the implant comprises a securing pin (fig. 17) and wherein the support comprises a sleeve 32 (fig. 16) with a protrusion (22) whose dimensions correspond practically to those of a recess provided in a head of the implant on which this support must be fixed (fig. 18, portion below element 23), such that the protrusion can be placed in a practically fitting manner in said recess (fig. 18), wherein the sleeve presents a second marker element (the marker being protrusions on the side of sleeve). Sala teaches the invention as substantially claimed and discussed above, however, does not specifically teach the marker element produces a strong contrast compared to the implant itself and wherein the marker element contains at least one of the metals from the group formed of tantalum, platinum and tungsten. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to make the marker element out of any known material used in the art since it has been held within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design

choice (*In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) MPEP 2144.07). Sala further teaches the support wherein the securing pin is coaxial to the support and is externally threaded (fig. 17). Sala further teaches wherein the support is mainly formed of a material which is transparent to x-rays (col. 6, ll. 39-44, col. 8, ll. 5-7, 54-55). It would have been obvious to one having ordinary skill in the art at the time of the invention to make the components of the support out of any known material used in the art since it has been held within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) MPEP 2144.07).

Response to Arguments

Applicant's arguments filed August 17, 2010 have been fully considered but they are not persuasive. Applicant argues that Ellis does not teach the limitation of fixing a marker element to a free end of an implant because Ellis teaches the marker element fully encased in the implant. However, the marker element taught by Ellis is fixed to the implant since it is attached to the implant. While Ellis does not teach the marker element being fixed in a detachable manner, the secondary reference of McCoy is used to teach the limitation of the marker element being fixed in a detachable manner. The applicant argues that the modification of McCoy teaches away from Ellis since Ellis teaches the marker to be fully encased. However, the marker element taught by McCoy is also fully encased as illustrated in fig. 1A. McCoy also teaches the marker element can be permanently attached to the implant (see abstract) which the embodiment taught by

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Ellis. Therefore, the modification of McCoy with Ellis does not teach away from Ellis since McCoy also teaches the same fully encased marker fixed to the implant as taught by Ellis along with a detachable marker. The applicant further argues that Ellis does not teach the marker attached to a free end of the implant, since the marker is attached to root portion, however, it is well known in the art that the root portion is the entire portion of the implant that is embedded in the jaw bone, Ellis is not specific as to what portion of the root portion the marker is attached to, the end portion that is embedded in the jaw bone, or the upper portion opposite the end portion, which the applicant argues is the free end. However, McCoy clearly teaches the marker element is attached to a free end of the implant. Applicant further argues that it would have not been obvious to one having ordinary skill in the art at the time of the invention to attach a supplementary detachable marker taught by McCoy with the invention taught by Ellis, however, the marker element taught by Ellis is being modified with the detachable marker element taught by McCoy. An additional marker is not being added to the invention of Ellis. As discussed above, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify means of attachment taught by Ellis with the detachable means taught by McCrory as a matter of obvious design choice since McCrory teaches a permanent attachment and detachable attachment of the marker element

1. The applicant further argues the McCoy does not teach the method of attaching a marker element to a dental implant that is fixed in the jawbone, however, Ellis is used to teach the limitation of attaching a marker element to a dental implant that is fixed in the

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jawbone. However, it is noted the McCoy does teach the invention used in the bone (col. 3, ll. 59-61).

2. Applicant further argues that Hattori teaches a stent for determining the location of an implant and not the implant is self, however, the prior art is used to teach the limitation of the implant in the jawbone as discussed above in detail. Hattori teaches the limitation of multiple markers in relation to a proposed implant 5 to determine multiple position of the implant (the proposed hole) by x-ray (col. 7, ll. 5-13).

11. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

3. Applicant further argues that regarding claim 15, that Sala does not teach a marker element of a support, however, it is noted that the notch on the top of the support is a marker element that would show up in an image, therefore the support does have a marker element. Further as discussed above in detail, it would have been obvious to one having ordinary skill in the art at make the support of any known material in the art at the time of the invention, such as a metal, which shows in an x-ray. It is well known in the art that supports such as the one taught by Sala are usually made of metal. Therefore the marker on the support is capable of producing a strong contrast in an image generated by x-rays compared to an implant. The device is capable of

functioning as claimed when the implant is made of a material that does not produce a strong contrast in an x-ray image.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HEIDI M. EIDE whose telephone number is (571)270-3081. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Heidi Eide
Examiner
Art Unit 3732

/Heidi M Eide/
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10/7/2010

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732